Supreme Court, U. S.
FILED
SEP 13 1978
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-421

GEORGE KIEVLAN, et al.,
Appellees,

vs.

DAHLBERG ELECTRONICS, INC., et al.,
Appellants.

On Appeal from the Court of Appeal of the State of California

First Appellate District

JURISDICTIONAL STATEMENT

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JURISDICTIONAL STATEMENT

This is a jurisdictional statement submitted in support of the appeal of Dahlberg Electronics, Inc. and Detection Sciences, Inc. (hereinafter collectively referred to as "Appellant").[1]

The format of this statement will conform to the order, lettering and numbering of Rule 15, to the extent applicable.

[1]Appellant Dahlberg Electronics, Inc. is a subsidiary of appellant Detection Sciences, Inc. For literary convenience, they are hereinafter referred to simply as "Appellant."

(a) Opinion below

The opinion of the Court of Appeal of the State of California is reported in 78 Cal.App.3d 951, 144 Cal.Rptr. 585. A copy of the opinion is also appended hereto as Exhibit A.

(b) Jurisdiction

(i) The Nature of the Proceedings and the Statutes pursuant to which they were brought.

This is an action for injunction brought pursuant to California Health and Safety Code Section 26463(m). The Superior Court of the State of California in and for the County of Santa Cruz issued an injunction which prohibits appellant from advertising that the hearing aids which it manufactures have any effect on hearing loss or deafness.

(ii) Judgment of the State Court.

The judgment of the Superior Court by which the injunction was issued was dated March 17, 1976 and entered March 22, 1976 in Judgment Book, Volume 148, page 220. Appellant filed a Notice of Appeal to the Court of Appeal of the State of California on May 19, 1976. The Court of Appeal's opinion was filed on March 21, 1978. The Court of Appeal denied a petition for rehearing on April 14, 1978. Appellant filed a petition for hearing in the Supreme Court of the State of California on May 1, 1978. The petition was denied on June 15, 1978 and the judgment of the Court of Appeal became final on that date. *American Ry. Exp. Co. v. Levee* (1923) 263 U.S. 19, 68 L.Ed. 140, 44 S.Ct. 11.

Notice of Appeal to this Court was filed in the Court of Appeal on September 1, 1978.

(iii) The Statutory Provisions Conferring Jurisdiction On This Court.

Jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257(2).

(iv) Cases which Sustain the Jurisdiction.

The decision of the Court of Appeal sustained the validity of the California statute as against appellant's claim that it violates the Constitution and laws of the United States. This decision has become final and therefore an appeal to this Court lies as a matter of right. *Huffman v. Pursue, Ltd.*, 420 U.S. 592, 43 L.Ed.2d 482, 95 S.Ct. 1200, rehearing denied 421 U.S. 971, 44 L.Ed.2d 463, 95 S.Ct. 1969.

Should this Court determine that an appeal does not lie, then appellant requests that this appeal and jurisdictional statement be treated as a petition for writ of certiorari.

(v) Statutes Involved.

This appeal involves California Health and Safety Code Section 26463(m) which states that:

> "It is unlawful for any person to advertise any drug or device represented to have any effect on any of the following conditions:
>
> . . .
>
> (m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." (Calif. Stat. 1970, c. 1573, p. 3252 § 5, Amended, Calif. Stats. 1971, c. 646, p. 1272, § 16).

Also involved is California Health and Safety Code Section 26465 which states:

> "Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the condi-

tions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health." (Calif. Stats. 1970, c. 1573, p. 3253, § 5.)

(c) Questions Presented

(1) Whether California Health and Safety Code Section 26463(m) has been pre-empted by the Food, Drug and Cosmetics Act (21 U.S.C. § 301 et seq.) as amended by the Medical Device Amendments of 1976 (21 U.S.C. § 360k).

(2) Whether a state statute and an injunction issued pursuant thereto prohibiting a hearing aid manufacturer from making any representations regarding the effect of its product on hearing loss or deafness are repugnant to the First Amendment to the United States Constitution.

(d) Statement of the Case

Appellees are individuals who claim to suffer from hearing loss.

This matter came before the Superior Court on appellees' motion for injunction by summary judgment. The motion was supported by copies of certain advertisements published by appellant. The basis of appellees' motion was that the advertisements violated Section 26463(m) of the California Health and Safety Code.

The Superior Court made its decision solely on the basis of the advertisements submitted and its interpretation of the statute. The Superior Court made no finding that the advertisements submitted were false or misleading.

The injunction which the court issued was not directed to the particular advertisements before it, but to any and

all advertising regarding the effectiveness of a hearing aid. It states:

> It Is Ordered, Adjudged And Decreed . . . that Defendants be and they hereby are permanently enjoined and restrained from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and deafness. (Tr. 308.)

The court also stated in its "Findings of Fact and Conclusions of Law":

> The use of the term hearing aid in and of itself is not a violation of Section 26463(m), and nothing contained therein precludes defendants or their dealers from advertising their place of business, that Dahlberg hearing aids are sold there, the prices of the hearing aids or any other information of that nature. (Tr. 305-6.)[2]

In order to understand the full significance of the injunction, the statutory definition of "advertisement" must be kept in mind.

> "Advertisement" means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase or use of any food, drug, device or cosmetic. (California Health and Safety Code Section 26002.)

The Court of Appeal affirmed the judgment. It rejected appellant's contention that the statute should be narrowly construed so as to prohibit only false and misleading claims. It held that the statute prohibits not only false and misleading representations that a hearing aid will cure

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[2]In view of the use of the summary judgment procedure, the making of findings of fact and conclusions of law was erroneous under California law. (Calif. Code of Civil Procedure Section 437c.)

hearing loss, but also truthful representations that a hearing aid may have a compensatory effect on hearing loss. The opinion states:

> "The statute is clear and unambiguous and does not exempt any so-called "compensatory effect." There is an exception included in the [California] Sherman Food, Drug and Cosmetics Law, which authorizes advertising of drugs and devices having a curative or therapeutic effect under certain conditions (§ 26465),[ ] however, this section makes no mention of compensatory effect and there is no claim by defendants that they had received any such authorization from the department exempting their product." (Opinion, pp. 3-4.)

The Court of Appeal's construction of the statute is binding on this Court. *U.S. v. Thirty-Seven (37) Photographs*, 402 U.S. 363, 28 L.Ed.2d 822, 91 S.Ct. 1400, rehearing denied 403 U.S. 924, 29 L.Ed.2d 702, 91 S.Ct. 2221.

The Court of Appeal also rejected appellant's contention that Section 26463(m) was pre-empted by federal law and regulation. In so doing, it held that the subject statute was a "prohibition" and not a "requirement" and that hearing aids were not "restricted devices" within the meaning of 21 U.S.C. § 352(r). These distinctions and terminology are discussed in detail below.

Finally, the Court of Appeal also held that the subject statute, as construed and applied by it, did not deny freedom of speech as guaranteed by the First Amendment. It based this holding upon its own independent finding of fact that ". . . the copies of the advertisements that are included in the record . . . were misleading in that they convey the impression that the hearing aid would have a curative or therapeutic effect." (Opinion, p. 5). It is essential to note, however, that the injunction was not limited to the particular advertisements in the record but covers

all advertising. Therefore, the court's conclusion, even if true, does not support its holding.

Appellant made its contentions that the statute was pre-empted and that it was unconstitutional for the first time in the Court of Appeal. They were not made in the Superior Court because the federal law had not yet been enacted and because this Courts' decision in *Virginia State Board of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc.* (1976) 425 U.S. 748, 48 L.Ed.2d 346, 96 S.Ct. 1817, had not yet been announced.

(e) The Questions Are Substantial

I. The statute has been pre-empted.

Section 26463(m) was clearly pre-empted by federal statute and regulations enacted and promulgated during the pendency of this appeal. The federal statute and regulations were called to the attention of the Court of Appeal in appellant's closing brief. The court agreed that the pre-emption issue was timely raised, (see *Meier v. Ross General Hospital* (1968) 69 Cal.2d 420, 423 (footnote 1); 71 Cal.Rptr. 903; *Cal-Dak Co. v. Sav-On-Drugs* (1953) 40 Cal. 2d 492, 496-497, 254 P.2d 497) but held that pre-emption had not occurred.

The error in this conclusion is readily apparent from an examination of the federal statute and regulations.

1. On May 28, 1976 the Medical Device Amendments of 1976 (P.L. 94-295) became law. The new law amended the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq., hereinafter "Act"). New section 521 of the Act (21 U.S.C. 360k) states that:

> **"Sec. 521. (a) Except as provided in subsection (b), no State or political subdivision of a State may estab-**

lish or continue in effect with respect to a device intended for human use any requirement—

(1) which is *different from, or in addition to,* any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Exempt Requirements

(b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not not cause the device to be in violation of any applicable requirements under this Act." (Emphasis added.)

2. New section 520(e) of the Act (21 U.S.C. 360j(e)(1)) states that the Secretary of Health, Education and Welfare may adopt regulations which restrict the sale, distribution or use of medical devices. Upon the adoption of such regulations, these devices are then known as "restricted devices."

3. On February 10, 1977 the Food and Drug Administration of the United States Department of Health, Education and Welfare (FDA) adopted new Rules and Regulations pertaining to hearing aid devices. (42 Fed. Reg. No. 31.) The regulations took effect on August 15, 1977. These regulations classify hearing aids as "restricted devices."[3]

4. Because hearing aids are "restricted devices" they are covered by the provisions of 21 U.S.C. § 352 pertaining to "misbranded drugs and devices." This section of the Act states in pertinent part that,

"A drug or device shall be deemed to be misbranded—...

(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer or distributer thereof includes in *all advertisements . . . a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contra-indications . . . .*" (Emphasis added.)

The Court of Appeal based its conclusion that pre-emption had not occurred upon two grounds: (a) that section 26463(m) embodies a "prohibition" rather than a "requirement" as referred to in 21 U.S.C. § 360k; and (b) that hearing aids are not "restricted devices." (See Opinion, p. 8.) Neither of these grounds has any validity.

A. The statute imposes a requirement "different from" and "in addition to" that of the federal act and is not a mere prohibition.

The first ground is a purely superficial distinction, based strictly upon semantics, and drawn without any regard to the intent of the Act. The language of 21 U.S.C. § 352(r)

[3]The Food and Drug Administration specifically stated when publishing the regulations that "Upon the effective date of the regulation, hearing aids will become 'restricted devices' under section 520(e) of the Federal Food, Drug and Cosmetic Act." (See 42 Fed.Reg. No. 31, at page 9291.)

reveals a clear intent to control the content of "all advertisements" of a "restricted device." Such advertisements *must contain* "a brief description of the intended uses of the device."

The intent of Congress is clearly contravened by any state law purporting to prohibit the manufacturer of a "restricted device" from describing its intended use. Yet this is precisely what section 26463(m), as construed by both the Superior Court and the Court of Appeal herein, does. It prohibits the hearing aid manufacturer from representing that the aid has "any effect," even a compensatory effect, on hearing loss. To say that this is only a "prohibition" as opposed to a "requirement" is to elevate form over substance. It requires one to indulge in the unrealistic assumption that hearing aids will simply not be advertised. Such assumption is not only naive, it is also contrary to the clear policy of Congress that such advertising is desirable. (See discussion, section D infra.) The statute is therefore "different from" and "in addition to" the Act.

The distinction which the Court of Appeal sets up is contrary to this Court's guidelines for determining whether pre-emption has occurred. As stated by this Court in *Jones v. Rath Packaging Co.* (1977) 430 U.S. 519, 51 L.Ed.2d 604, 97 S.Ct. 1305,

> Where, as here, the field which Congress is said to have pre-empted has been traditionally occupied by the States, see, eg., U.S. Const Art I, § 10; Patapsco Guano Co. v. North Carolina, 171 US 345, 358, 43 L Ed 191, 18 S Ct 862 (1898), "we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Rice v Santa Fe Elevator Corp. 331 US 218, 230, 91 L Ed 1447, 67 S Ct 1146 (1947). This assumption provides assurance that "the federal-state balance," United States v Bass, 404 US 336, 349, 30 L Ed 2d 488, 92 S Ct 515 (1971),

> will not be disturbed unintentionally by Congress or unnecessarily by the courts. But when Congress has "unmistakably . . . ordained," Florida Lime & Avocado Growers, Inc. v Paul, 373 US 132, 142, 10 L Ed 2d 248, 83 S Ct 1210 (1963), that its enactments alone are to regulate a part of commerce, state laws regulating that aspect of commerce must fall. This result is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. City of Burbank v Lockheed Air Terminal, Inc. 411 US 624, 633, 36 L Ed 2d 547, 93 S Ct 1854 (1973); Rice v Santa Fe Elevator Corp., supra, at 230, 91 L Ed 1447, 67 S Ct 1146.

In *Jones* certain packages of bacon were ordered removed from sale pursuant to a California weight labelling statute and regulations which required that the average weight of packages in a lot of any commodity shall not be less at the time of sale than the net weight stated on the packages. The company which had packaged the bacon instituted actions against certain state officials seeking an injunction against enforcement of the state laws and a declaration that such laws were pre-empted by federal laws regulating net weight labelling. The California laws made no allowances for reasonable variations from stated weight resulting from loss of moisture during the course of good distribution practices, but the federal law provided that "reasonable variations" between actual weight and the weight stated on the label could be permitted by regulations prescribed by the Secretary of Agriculture and the Secretary's regulations did permit "reasonable variations" resulting from loss of moisture during the course of good distribution practices.

The question presented was basically the same as the one herein; i.e., whether the State of California had attempted to impose "requirements in addition to, or different than," those made under a federal law.[4] The subject statute, section

[4] Federal Meat Inspection Act, as amended by the Wholesale Meat Act, 21 U.S.C. §§ 601 et seq.

12211 of the California Business and Professions Code, was couched in *prohibitory* language, much the same as the state statute herein.[5] Nevertheless, this Court held that it was pre-empted by a "labelling requirement" contained in the federal statute. In so holding, this Court looked to the manifest purpose and objective of the federal law, i.e., to make

[5]"Each sealer shall, from time to time, weigh or measure packages, containers or amounts of commodities sold, or in the process of delivery, in order to determine whether the same contain the quantity or amount represented and whether they are being sold in accordance with law.

"The director [of agriculture] is hereby authorized and directed to adopt and promulgate necessary rules and regulations governing the procedures to be followed by sealers in connection with the weighing or measuring of amounts of commodities in individual packages or containers or lots of such packages or containers, including the procedures for sampling any such lot, and in determining whether any package or container or a lot of such packages or containers complies with the provisions of this section. . . .

"Any such rule or regulation, or amendment thereof, shall be adopted and promulgated by the director in conformity with the provisions of Chapter 4.5 (commencing with Section 11371), of Part 1 of Division 3 of Title 2 of the Government Code; provided, that *the average weight or measure of the packages or containers in a lot of any such commodity sampled shall not be less, at the time of sale or offer for sale, than the net weight or measure stated upon the package,* and provided further, that said rules or regulations applicable to food, as defined in Section 26450 of the Health and Safety Code, insofar as possible, shall not require higher standards and shall not be more restrictive than regulations, if any, promulgated by the Department of Health, Education, and Welfare, Food and Drug Administration, under the provisions of the Federal Food, Drug and Cosmetic Act.

"Any lot or package of any such commodity which conforms to the provisions of this section shall be deemed to be in conformity with the provisions of this division relating to stated net weights or measures.

"Whenever a lot or package of any commodity is found to contain, through the procedures authorized herein, a less amount than that represented, the sealer shall in writing order same off sale and require that an accurate statement of quantity be placed on each such package or container before same may be released for sale by the sealer in writing. The sealer may seize as evidence any package or container which is found to contain a less amount than that represented." (Emphasis added.)

allowances for loss of weight resulting from moisture loss during the course of good distribution practice. It rejected the argument of the county director of weights and measures which was based upon a narrow construction of the term "labelling requirement."

> Petitioner Jones seeks to avoid this result by arguing that the FMIA's provisions governing the accuracy of the required net quantity statements are not "labeling requirements" within the meaning of § 408. He contends that "labeling" refers only to the format and placement of information, not to its content. Requirements relating to accuracy, according to Jones, deal with the problem of misbranding, and § 408 grants the States concurrent jurisdiction over that subject.
>
> We agree with the Court of Appeals that this argument is "strained." 530 F2d, at 1314 n 25. Nothing in the Act suggests the restrictive meaning petitioner ascribes to the phrase "labeling requirements." To the contrary, § 7(b) requires that the product bear specified information, see supra, at 528-529, 51 L Ed 2d 616, and § 1(p) of the FMIA, 21 USC § 601(p) [§ 2, 21 USCS § 601(p)], makes clear that any material bearing that information is part of the product's labeling. It twists the language beyond the breaking point to say that a law mandating that labeling contain certain information is not a "labeling requirement."
>
> We therefore conclude that with respect to Rath's packaged bacon, § 12211 and Art 5 are pre-empted by federal law.

(430 U.S. at p. 532.)

B. Hearing aids have been classified as "restricted devices."

The second ground relied upon which the Court of Appeal predicated its conclusion that pre-emption had not occurred, i.e. that hearing aids are not "restricted devices", need not detain this Court for more than a moment. The FDA, in adopting its regulations expressly

classified hearing aids as "restricted devices". (See 42 Fed. Reg. No. 31, p. 9291.) The FDA is authorized to make this classification. (21 U.S.C. 360j (e)(1).)

C. The statute has not been exempted.

The Court of Appeal's opinion that section 26463(m) has not been pre-empted no doubt came as a surprise to the California Department of Health which filed an application dated July 19, 1976, entitled "Application for Exemption of California Medical Device Requirements from Pre-emption by Federal Medical Device Amendments of 1976 (Section 521(a))" with the Commissioner of Food and Drugs. The application of the Department of Health (which covers many statutes) is still pending before the FDA.

The FDA by notices of February 15, 1977, 42 Fed.Reg. No. 31, page 9186, and July 28, 1978, 43 Fed.Reg. No. 146, page 33182, has tentatively proposed to grant the application, but has invited special comment regarding the subject statute.[6]

D. The statute is in direct conflict with the Act.

The statute prohibits the very advertising which the federal Act and regulations require.

As shown above, the Act specifically requires that all hearing aid advertising *shall* include a brief statement as to intended uses of the device, i.e., what effect it will have.

In addition, the regulations (21 C.F.R. §§ 801.420 and 801.421) impose several other duties upon hearing aid

[6]The FDA's authority to grant or deny an exemption is not questioned. Indeed, Congress may authorize federal administrative agencies to directly pre-empt state laws by the promulgation of administrative regulations. (See, *e.g., Burbank v. Lockheed Air Terminal, Inc.* (1973) 411 U.S. 624, 36 L.Ed.2d 547, 93 S.Ct. 1854.)

manufacturers and distributors. Among these duties, the manufacturer or distributor must develop a User Instructional Brochure and provide a copy thereof to each prospective purchaser of a hearing aid. This brochure *must* contain certain information and warnings, including specific instructions for use of the hearing aid, a statement that a hearing aid will not restore normal hearing, advice that a person suffering from a hearing loss should consult a licensed physician, preferably an ear specialist, before purchasing a hearing aid, and that federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation or signed a waiver thereof. The brochure *must* contain "a statement that in most cases infrequent use of a hearing aid does not permit a user to obtain full benefit from it." (21 C.F.R. § 801.420 (ix).)

These required statements are clearly advertising within the meaning of California Health and Safety Code Section 26002, i.e., they are representations which are likely to induce the purchase of a hearing aid. As such they fall within the scope of the statute and the injunction, and there is a clear conflict between federal and state laws. Therefore, the state law is superseded. U.S. Const., Art. VI.

E. The statute frustrates the full accomplishment of the objectives of Congress.

Even if there were no direct conflicts, the state statute would still be pre-empted for another reason. As *Jones, supra,* reaffirms, a state statute is overridden by a federal statute whenever it would frustrate the full accomplishment of the objectives of Congress. This is precisely the situation in the instant case where the objective of Congress is to stimulate the flow of information regarding the value of hearing aids.

Jones discussed the question of conflicting federal and state legislation in these terms:

> Congressional enactments that do not exclude all state legislation in the same field nevertheless override state laws with which they conflict. U.S. Const, Art VI. The criterion for determining whether state and federal laws are so inconsistent that the state law must give way is firmly established in our decisions. Our task is "*to determine whether, under the circumstances of this particular case, [the State's] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.*" Hines v Davidowitz, 312 US 52, 67, 85 L Ed 581, 61 S Ct 399 (1941). Accord, De Canas v Bica, 424 US 351, 363, 47 L Ed 2d 43, 96 S Ct 933 (1976); Perez v Campbell, 402 US 637, 649, 29 L Ed 2d 233, 91 S Ct 1704 (1971); Florida Lime & Avocado Growers, Inc. v Paul, supra, at 141, 10 L Ed 2d 248, 83 S Ct 1210; id., at 165, 10 L Ed 2d 248, 83 S Ct 1210 (White, J., dissenting). This inquiry requires us to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written. See De Canas v Bica, supra, at 363-365, 47 L Ed 2d 43, 96 S Ct 933; Swift & Co. v Wickham, 230 F Supp 398, 408 (SDNY 1964), appeal dismissed, 382 US 111, 15 L Ed 2d 194, 86 S Ct 258 (1965), affd on further consideration, 364 F2d 241 (CA2 1966), cert denied, 385 US 1036, 17 L Ed 683, 87 S Ct 776 (1967).
>
> (430 U.S. at pp. 525-526, emphasis added.)

See also *Ray v. Atlantic Richfield Company* (1978) ..... U.S. ....., ... L.Ed.2d ....., 98 S.Ct. 988.

The lower courts herein have adopted the position that the law must shield the prospective purchaser from performance claims for hearing aids and have interpreted the statute accordingly. But it is the policy of the federal law and regulations to require the manufacturer to make performance claims, i.e. to tell the customer what the hearing aid will do and at the same time to warn him what it will not do.

In a prefatory statement to the new regulations, the FDA states:

> The Commissioner sees no value in characterizing hearing aid dispensers solely as "sales persons," or in minimizing the importance of "selling" as it relates to motivating persons to try amplification. Often a person with a hearing impairment lacks the motivation to try a hearing aid or believes a social stigma is attached to wearing a hearing aid (Ref. 4). Although there are a number of documented cases of excessive and abusive sales practices, this is not to say that some selling practices and techniques such as a trial-rental or purchase-option plan, which strengthen motivation to try a hearing aid, are inherently bad. When the number of hearing-impaired persons who currently wear hearing aids is contrasted with the number of people in the United States with a hearing impairment who could be helped by a hearing aid, it is clear that many people are reluctant to acknowledge their hearing impairment or to seek assistance. *Ethical selling practices that provide the potential hearing aid user with incentives to try a hearing aid are therefore to be encouraged.* (42 Fed. Reg. No. 31, p. 9387, emphasis added.)

Appellant submits that the state statute, as interpreted and applied herein, clearly " 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the Congress.' " (*Jones v. Rath Packing Co., supra,* p. 526.) It prevents the manufacturer from communicating the intended use and benefit of a hearing aid to the potential user. The objective of the federal law to

reach out to the hard of hearing because of their reluctance to seek help is frustrated by this statute.

II. The statute and injunction infringe upon Appellant's right to freedom of speech under the First Amendment of the United States Constitution.

1. Commercial speech is protected by the First Amendment to the United States Constitution.

This Court has recently established the principle that "commercial speech" is protected by the First Amendment to the United States Constitution. *Virginia State Board of Pharmacy, et al. v. Virginia Citizens Consumer Council, Inc.* (1976) 425 U.S. 748, 48 L.Ed.2d 346, 96 S.Ct. 1817 (hereinafter referred to as "the Virginia case").[7] In the *Virginia* case, a consumer organization brought suit against the Virginia State Board of Pharmacy challenging the validity under the First and Fourteenth Amendments of a Virginia statute declaring it to be unprofessional conduct for a licensed pharmacist to advertise the prices of prescription drugs. This Court struck down the statute in an opinion which states, in part:

> Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what

[7]Subsequent to the *Virginia* case, numerous additional cases have sustained free speech claims for advertising. *E.g., Bates v. Arizona State Bar*, 433 U.S. 350, 53 L.Ed.2d 810, 97 S.Ct. 269-1; *Linmark Associates, Inc. v. Township of Willingboro*, U.S. , 52 L.Ed.2d 55, 97 S.Ct. 1614; *Jacoby v. State Bar of California*, 19 Cal. 3d 359, 377, 138 Cal.Rptr. 77; *Board of Medical Examiners v. Terminal-Hudson Electronics*, 73 Cal.App.3d 376, 140 Cal.Rptr. 757; *Health Systems Agency of Northern Virginia v. Virginia State Board of Medicine* (E.D. VA. 1976) 424 F.Supp. 267.

> product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable. (96 S.Ct. p. 1827).

2. The statute and the injunction are overly broad.

A. All representations for the purpose of inducing a purchase are deemed advertising.

The definition of advertising in California Health and Safety Code Section 26002 is extremely broad.

> "Advertisement" means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase or use of any food, drug, device or cosmetic.

This broad-sweeping definition clearly prohibits any and all forms of expression, written or oral, intended to induce a sale to the public of a drug or device of the type mentioned. *People v. Hohensee* (1967) 251 Cal.App.2d 193, 59 Cal.Rptr. 234. Therefore, the effect of Section 26463, as construed and applied in this case, is to prohibit the manufacturer of a hearing aid from informing the consumer what his product does. The seller or distributor is similarly restricted. He can say "I sell hearing aids for one hundred dollars. My store is located at 1 Main Street". But when the customer comes in and asks, "How will it help me?", he has to say, "I'm sorry, but I can't tell you." This restriction is invalid under the *Virginia* case.

B. There is no provision for obtaining permission to advertise a drug or device.

Section 26463 is not mitigated by the provisions of Section 26465 which contemplate the granting of permission to advertise in certain cases, for such permission depends upon the uncontrolled discretion of the Department of Public Health ("department"). Thus, Section 26465 states:

> Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health.

The statute affords no protection at all for the truthful seller of a worthwhile drug or device. The department must first "determine" that it is safe and effective. But there is no requirement that the department hold a hearing to make such determination and no provision for any interested party to obtain such a hearing before any other agency or tribunal. There is not even a duty imposed upon the department to *consider* a particular drug or device.[8]

There is no procedure to review the department's exercise of discretion or even to compel the exercise of *any* discretion. Thus, there is no procedural safeguard against

[8]If the department does determine that a particular type of self-medication is safe and effective, then it is supposed to authorize advertisement thereof "by regulation". The department is authorized in Section 102 to issue regulations pursuant to procedures set forth in the Government Code. Under these provisions, interested parties may petition for the adoption of regulations, but the governmental agency may deny the petition without a hearing. (See Calif. Government Code Secs. 11426 and 11427.)

suppression of truthful information, and this renders the statute unconstitutional.

In addition, Section 26465 would not even be applicable to hearing aids because they are not "curative or therapeutic" devices.

C. The statute prohibits truthful representations as well as false or misleading ones.

Falsity is not an element of the offense proscribed by Section 26463. *Neslen v. Board of Health* (1945) 70 Cal. App.2d 202, 160 P.2d 862.[9]

Accordingly the statute on its face is overbroad and a claim of unconstitutionality on that ground should be entertained. Appellant should be permitted to challenge the constitutionality of the statute without a showing that its particular advertisements were truthful and thus protected.

> Such claims of facial overbreadth have been entertained in cases involving statutes which, by their terms, seek to regulate "only spoken words." Gooding v Wilson, 405 US 518, 520, 31 L Ed 2d 408, 92 S Ct 1103 (1972). See Cohen v California, 403 US 15, 29 L Ed 2d 284, 91 S Ct 1780 (1971); Street v New York, 394 US 576, 22 L Ed 2d 572, 89 S Ct 1354 (1969); Brandenburg v Ohio, 395 US 444, 23 L Ed 2d 430, 89 S Ct 1827 (1969); Chaplinsky v New Hampshire, 315 US 568, 86 L Ed 1031, 62 S Ct 766 (1942). In such cases, it has been the judgment of this Court that the possible harm to society in permitting some unprotected speech to go unpunished is outweighed by the possibility that protected speech of others may be muted and perceived grievances left to fester because of the possible inhibitory effects of overly broad statutes. . . .

[9]False and misleading advertising is covered by another section of the Health and Safety Code, i.e., Section 26460, which states: "It is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. An advertisement is false if it is false or misleading in any particular."

Facial overbreadth claims have also been entertained where statutes, by their terms, purport to regulate the time, place, and manner of expressive or communicative conduct, see Grayned v City of Rockford, supra, at 114-121, 33 L Ed 2d 222; Cameron v Johnson, 390 US, at 617-619, 20 L Ed 2d 182; Zwickler v Koota, 389 US 241, 249-250, 19 L Ed 2d 444, 88 S Ct 391 (1967); Thornhill v Alabama, 310 US 88, 84 L Ed 1093, 60 S Ct 736 (1940), and where such conduct has required official approval under laws that delegated standardless discretionary power to local functionaries, resulting in virtually unreviewable prior restraints on First Amendment rights. See Shuttlesworth v Birmingham, 394 US 147, 22 L Ed 2d 162, 89 S Ct 935 (1969); Cox v Louisiana, 379 US 536; 553-558, 13 L Ed 2d 471, 85 S Ct 453 (1965); Kunz v New York, 340 US 290, 95 L Ed 280, 71 S Ct 312 (1951); Lovell v Griffin, 303 US 444, 82 L Ed 949, 58 S Ct 666 (1938).

(*Broadrick v. Oklahoma* (1973) 413 U.S. 601, 37 L.Ed.2d 830, 93 S.Ct. 2908.)

This Court's pronouncements on the doctrine of overbreadth in the newly protected area of commercial speech have heretofore been somewhat guarded. Thus, in *Bates v. State Bar of Arizona,* 433 U.S. 350, 53 L.Ed.2d 810, 97 S.Ct. 2691, the Court stated,

> . . . the justification for the application of overbreadth analysis applies weakly, if at all, in the ordinary commercial context. As was acknowledged in Virginia Pharmacy Board v Virginia Consumer Council, 425 US, at 771 n 24, 48 L Ed 2d 346, 96 S Ct 1817, there are "common-sense differences" between commercial speech and other varieties. See also id., at 775-781, 48 L Ed 2d 346, 96 S Ct 1817 (concurring opinion). Since advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation. (433 U.S. 380-381)

Appellant submits, however, that there are compelling reasons in the instant case for applying the overbreadth doctrine. First, it involves public health and Congress and the FDA have indicated a definite desire to have information regarding the performance of hearing aids disseminated to potential users. The state statute clearly conflicts with the federal Act and frustrates its objective. Secondly, the desired speech is not only "susceptible to being crushed by overbroad regulation", it has *in fact been crushed.* The statute, as construed and applied by the California courts, restrains appellant from *all* performance claim advertising. And of course if appellant is restrained then all other manufacturers will be similarly restrained. Such restraint is intolerable. The state may not use its police power to prohibit *all* performance claim advertising of medical drugs or devices. Less restrictive alternatives, e.g. California Health and Safety Code Section 26460 prohibiting false and misleading advertising, are available to the state. Other reasonable means are also spelled out in the federal regulations, e.g., the requirement of a medical evaluation before a sale may be made.

In an area affecting First Amendment rights precision of regulation is the touchstone, and statutes must be narrowly drawn so that the precise evil is exposed.

Keyishian v. Board of Regents (1967) 385 U.S. 589, 17 L.Ed.2d 629, 87 S.Ct. 675;

Interstate Circuit, Inc. v. Dallas (1968) 390 U.S. 676, 20 L.Ed.2d 225, 88 S.Ct. 1298;

Shuttlesworth v. Birmingham (1968) 394 U.S. 147, 22 L.Ed.2d 162, 89 S.Ct. 935;

Elfbrandt v. Russell (1966) 384 U.S. 11, 16 L.Ed.2d 321, 86 S.Ct. 1238;

Griswold v. Connecticut (1965) 381 U.S. 479, 14 L.Ed. 2d 510, 85 S.Ct. 1678.

Where First Amendment rights are involved, the courts must examine and test statutes more closely than otherwise.

Ashton v. Kentucky (1966) 384 U.S. 195, 16 L.Ed.2d 469, 86 S.Ct. 1407.

Appellant submits that Section 26463 cannot withstand the close scrutiny required by First Amendment standards. It is overbroad on its face and must be struck down.

D. The injunction goes beyond the particular advertising which was exhibited to the court and presents a further problem of overbreadth.

Because the injunction merely paraphrases the statute, it goes beyond the particular advertising which gave rise to the action and is also patently overbroad. Indeed the injunction presents the problem of overbreadth in a more compelling way than the statute standing alone. The overbreadth doctrine permits litigants ". . . to challenge a statute not because their own rights of free expression are violated, but because of a judicial prediction or assumption that the statute's very existence may cause others not before the court to refrain from constitutionally protected speech or expression." *Broadrick v. Oklahoma* (1973) 413 U.S. 601, 612, 37 L.Ed.2d 830, 93 S.Ct. 2908. But here appellant's own right of free expression *is* directly violated by the injunction. Therefore, appellant submits that the overbreadth doctrine becomes all the more applicable herein. As stated in *Carroll v. Commissioners of Princess Anne* (1968) 393 U.S. 175, 183-184, 21 L.Ed.2d 325, 89 S.Ct. 347,

> An order issued in the area of First Amendment rights must be couched in the narrowest terms that will accomplish the pin-pointed objective permitted by constitutional mandate and the essential needs of the public order. In this sensitive field, the State may not employ "means that broadly stifle fundamental personal liberties when the end can be more narrowly achieved." Shelton v. Tucker, 364 U.S. 479, 488, 5 L. Ed.2d 231, 237, 81 S.Ct. 247 (1969). In other words, the order must be tailored as precisely as possible to the exact needs of the case.

E. The extent of First Amendment protection for product performance claims as opposed to price information should be spelled out.

The Court's decisions in the commercial speech area have heretofore been limited to situations involving price information. Nevertheless, as stated in *Virginia, supra,* 425 U.S. at 765,

> Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

As this language indicates, there is no logical reason why information concerning the performance of the product should be any less protected than information concerning the price. Common sense tells us that unless the nature and performance of the product can be communicated, the free flow of price information will be of little value. Again appellant submits that this is especially true in a case where a federal policy in favor of disseminating the information has been enunciated.

3. Sections 26463 and 26465 constitute an invalid prior restraint on freedom of expression.

Sections 26463 and 26465 prohibit the manufacturer and the seller of a drug or device of the types described from making any statement, even if true, for the purpose of

inducing a sale thereof unless the department has first authorized the statement. This is a classic system of prior restraint of expression. In light of the *Virginia* case, it comes before the court with a heavy presumption against its constitutional validity. *Heller v. New York* (1973) 413 U.S. 483, 37 L.Ed.2d 745, 93 S.Ct. 2789; *Organization for a Better Austin v. Keefe* (1971) 402 U.S. 415, 29 L.Ed. 2d 1, 91 S.Ct. 1575.

The presumption may be overcome only where adequate safeguards against suppression of truthful information have been provided. Thus in *Poulos v. New Hampshire* (1953) 345 U.S. 395, 97 L.Ed. 1105, 73 S.Ct. 760, reh. den. 345 U.S. 978, 97 L.Ed. 1392, 73 S.Ct. 1119, an ordinance requiring a license to conduct religious services in a park was held valid because of the ready availability of judicial relief to test the reasons for refusal. But in *Freedman v. Maryland, supra,* the prior licensing of motion pictures was not allowed where the exhibitor was required to withhold showing the film until he had first obtained a judicial determination that it was not obscene with no assurance that such determination would be speedy. See also *Staub v. Baxley* (1958) 355 U.S. 313, 2 L.Ed.2d 302, 78 S.Ct. 277, and *Neimotko v. Maryland* (1951) 340 U.S. 268, 95 L.Ed. 267, 71 S.Ct. 325.

Here the California legislature has enacted a statute which imposes prior restraints on commercial speech and provides no safeguards at all against suppression of truthful information. A statute having this effect cannot be sustained.

(h and i) Opinions, Judgment, and Orders

In addition to the opinion of the Court of Appeal which is appended as Exhibit A, the opinion and judgment of the Superior Court are appended hereto as Exhibits B and C. The order of the Court of Appeal denying rehearing is appended hereto as Exhibit D and the order of the Supreme Court of California denying a hearing is appended hereto as Exhibit E.

A copy of the Notice of Appeal to this Court which was filed in the Court of Appeal is appended hereto as Exhibit F.

Respectfully submitted,

STANLEY WALSH,
JORDAN, WALSH, LAWRENCE,
DAWSON & CARBONE,
Attorneys for Appellants Dahlberg Electronics, Inc., and Detection Sciences, Inc.

(Exhibits Follow)

Exhibit A

CERTIFIED FOR PUBLICATION
In the Court of Appeal
State of California
First Appellate District,

Division Four

1 Civil No. 40017
(Sup.Ct.No. 51868)

George Kievlan, et al.,
Plaintiffs, Respondents and Appellants,
vs.
Dahlberg Electronics, a corporation, et al.,
Defendants, Appellants and Respondents.

[Filed Mar. 21, 1978]

OPINION

Dahlberg Electronics, Inc., and Detection Sciences, Inc., defendants, appellants and respondents,[1] appeal from a judgment[2] permanently enjoining them "from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and

[1]As both parties are appellants and respondents, for literary convenience we will refer to Dahlberg Electronics, Inc., and Detection Sciences, Inc., as defendants, and Kievlan and the other senior citizens as plaintiffs.

[2]The judgment was entered following plaintiffs' motion for summary judgment. The defendants agree there is no contested issue of fact in the case, only issues of law.

deafness." George Kievlan, et al., plaintiffs,[3] respondents and appellants, have appealed from the judgment on the ground that attorney's fees were not awarded.

Dahlberg Electronics, Inc., is a Minnesota corporation which manufactures "Miracle Ear" and "Magic Ear" hearing aids. Dahlberg is a wholly owned subsidiary of Detection Sciences, Inc., a Minnesota corporation. Dahlberg sells a substantial number of hearing aids in California through retail hearing aid dealers. Dahlberg advertises its hearing aids extensively in national publications. Other advertisements are distributed by Dahlberg to its local dealers.

Defendants have appealed from the judgment on the grounds (1) the trial court erred in its construction and application of section 26463 of the Health and Safety Code; (2) that the statute is unconstitutional; and (3) that state regulation of hearing aid advertising has been preempted by federal law and regulations.

Plaintiffs have appealed on the ground that the judgment did not award attorney's fees.

I

Defendants contend that the injunction does not merely prohibit advertising that their hearing aid would have a curative or therapeutic effect but that it also prohibits them from advertising that their hearing aids have *any effect*, including a compensatory effect on hearing loss. Defendants argue that section 26463 is concerned with false and misleading representations and that it is not the intent of the code section to prohibit advertising that a product will compensate for a physical disability without representing it will cure or remedy it. The difficulty with defendants' argument is that neither statute nor the judgment make any reference

[3]Plaintiffs allege that they are six senior citizens who have brought this suit on behalf of themselves and the general public.

to compensatory effect, so the argument is not relevant. The code section, 26463, subdivision (m), provides: "It is unlawful for any person to advertise any drug or device represented to have any effect in any of the folowing conditions, disorders, or diseases:

"...

"(m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness."

"The statute is clear and unambiguous and does not exempt any so-called 'compensatory effect.' There is an exception included in the Sherman Food, Drug and Cosmetics Law, which authorizes advertising of drugs and devices having a curative or therapeutic effect under certain conditions (§ 26465),[4] however, this section makes no mention of compensatory effect and there is no claim by defendants that they had received any such authorization from the department exempting their product."

Defendants also claim a hearing aid is not a "device" within the meaning of Health and Safety Code section 26009, which provides: " 'Device' means any instrument, apparatus, or contrivance, including any component part, product, or by-product of a device, or accessory, which is used, or intended for use, for any of the following:

"(a) In the diagnosis, cure, mitigation, treatment, or prevention of disease in man or any other animal.

[4]Section 26465 of the Health and Safety Code provides:

"Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in Section 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health."

"(a) To affect the structure or any function of the body of man or any other animal." Without question, a hearing aid is an instrument or apparatus used in the *mitigation* of hearing diseases and affects the bodily functioning of the person using it. We also note that Business and Professions Code section 3305 defines a hearing aid as: "... any wearable instrument or device designed for, or offered for the purpose of, aiding or compensating for impaired human hearing."

Defendants contend that hearing aid dispensers are regulated by provisions of Division 2, chapter 7.5 (commencing with § 3300) of the Business and Professions Code. This chapter provides for the licensing of persons who engage in the practice of fitting and selling hearing aids. Defendants do not contend that they are licensed under this act. Furthermore, defendants cite no authority to support their positions that chapter 7.5 and the Sherman Act are mutually exclusive. They are in fact complimentary and in a proper case both can apply.

II

Defendants contend that section 26463 denies freedom of speech as guaranteed by the First Amendment of the United States Constitution, citing *Va. Pharmacy Bd. v. Va. Consumer Council* (1976) 425 U.S. 748. However, we need not reach this problem.

The judgment enjoined defendants from advertising their hearing aids by representing that the hearing aids have any effect on diseases or disorders of the ear including hearing loss and deafness. The Sherman Act, section 26460, declares it is unlawful for any person to disseminate any false advertisement of any device and declares an advertisement is false if it is false or misleading in any particular. It is clear from the copies of the advertisements that are included in the record that the advertisements were misleading in that

they convey the impression that the hearing aid would have a curative or therapeutic effect. The defendants in their brief concede that hearing aids do not have a curative or therapeutic effect. The *Virginia State Board of Pharmacy* case is of no help to defendants. As a concurring opinion points out the court's decision did not preclude state and federal regulation of false or deceptive advertising. The injunction is thus proper.

III

Defendants' third contention is that state regulation of hearing aid advertising has been preempted by federal law and regulation.[5] On May 28, 1976, the Medical Device Amendments of 1976 (90 Stat. 540) were enacted, amending the Federal Food, Drug and Cosmetics Act. (21 U.S.C., § 301 et seq.) As amended, section 360K of that act provides:

"(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

"(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

"(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

[5]This point was timely raised notwithstanding the fact that it was mentioned for the first time in defendants' closing brief. The implementing regulations were not approved until February 10, 1977, two months after defendants had filed their opening brief. Where a point of law which is determinative of an appeal is announced after the filing of the opening brief, the appellant is permitted to present the point in a closing or supplemental brief. (Meier v. Ross General Hospital (1968) 69 Cal.2d 430, 423-424, fn. 1.)

"Exempt Requirements

"(b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

"(1) the requirement is more stringent that a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

"(2) the requirement—

"(A) is required by compelling local conditions, and

"(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter. June 25, 1938, c. 675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574." Implementing regulations concerning hearing aid devices were approved by the Food and Drug Administration on February 10, 1977, and became effective August 15, 1977. (21 C.F.R., §§ 801.420, 801.421.) According to the language of section 360K, the preemptive effect of the act upon state action, with respect to hearing aids, is to be determined by the three-way test (1) whether the state action is a "requirement" and, if it is, (2) whether it is "different from, or in addition to" any requirement of the act on that subject *and* (3) whether it "relates to the . . . effectiveness" of hearing aids. (21 U.S.C., § 360K, subd. (a).) Because the three factors appear in a conjunctive context (see *ibid.*), all three must appear before a court may declare that the act preempts Health and Safety Code section 26463, subdivision (m), in the hearing aid business.

Section 26463, subdivision (m), meets the third test to the categorical extent that it "relates to the . . . effectiveness" of hearing aids by prohibiting representations on this subject in copy which advertises them for sale. But, because it does this and no more, it fails the first test of preemption because it is a flat *prohibition*: it is not a "requirement."

If it may be treated as a "requirement," its effect is nevertheless limited to the *advertising* of hearing aids for sale. The federal act reaches the subject of advertising, but of "restricted devices" only. (21 U.S.C., § 352, subd. (r).) By the act's terms, "restricted devices" are those which the Secretary of Health, Education and Welfare determines, by regulation, may be sold upon licenses-practitioner prescription only. (21 U.S.C., § 360j, subd. (e)(1). For congressional intent on this precise subject, see 1976 U.S. Code Cong. & Admin. News, No. 3, Medical Device Amendments of 1976 [commencing at p. 1070], pp. 1086, 1113-1114.)

Defendants have not shown that the secretary has classified hearing aids as "restricted devices." The federal act itself thus includes no "requirement" concerning the advertising of hearing aids. No such "requirement" appears in the implementing regulations adopted by the secretary, which have nothing to do with advertising. (See 21 C.F.R., §§ 801.420-801.421.) Health and Safety Code section 26463, subdivision (m), cannot be "different from, or in addition to," a "requirement" of the act which does not exist. The second test of its preemption by the act therefore fails as well. Thus, section 26463 is not preempted by federal law.

IV

Plaintiffs contend that the trial court erred in refusing to award them attorney's fees. They contend the trial court

had the power to award attorney's fees under three theories: (1) the "substantial benefit" rule, (2) the private attorney general concept, and (3) the newly enacted Code of Civil Procedure section 1021.5, which became effective January 1, 1978.

Applicability of each of these theories of recovery depends on the facts of the particular case. At the time this case was tried, August 1975, *Mandel v. Hodges* (1976) 54 Cal.App.3d 596, and *Serrano v. Priest* (1977) 20 Cal.3d 25, modified 20 Cal.3d 190a, had not been decided and Code of Civil Procedure section 1021.5 had not been enacted. Neither the trial court nor the attorneys had the benefit of these authorities before them and the court specifically based its ruling, denying attorney's fees, on the apparent state of the law at that time. The judgment must, therefore, be reversed as to the issue of attorney's fees and the matter remanded to the trial court on that issue for further proceedings.

Plaintiffs contend that Code of Civil Procedure section 1021.5 would not be applicable as it was not in effect at the time of trial. As stated in *Olson v. Hickman* (1972) 25 Cal. App.3d 920, 922: "Respondent . . . invokes the general rule of construction which frowns upon statutory retroactivity in the absence of a clear legislative direction. The rule has no application here. Section 800 [of the Government Code][6] classes itself as an ancillary provision, creating no new cause of action. It is procedural only. A lawsuit is governed by a change in procedural rules made during its pendency, and the suit is pending until its final determination on appeal." Section 1021.5 does not create a new cause of action; it is ancillary to the underlying cause. The cases cited by defendants are not in point, they involve changes that

[6]Government Code section 800 provides for the award of attorney's fees under certain circumstances in any civil action against a government agency or officer.

affect the cause of action. Section 1021.5 is not rendered inapplicable to the present case solely because of its effective date.

The judgment is reversed insofar as it does not provide for attorney's fees and the cause is remanded to the trial court for further proceedings on this issue only. In all other respects the judgment is affirmed. Plaintiffs to recover costs on appeal.

CERTIFIED FOR PUBLICATION

Caldecott, P. J.

We concur:

Rattigan, J.

Ragan, J.*

*Assigned by the Chairperson of the Judicial Council.

Exhibit B

Superior Court of the State of California
for the County of Santa Cruz

No. 51868

George Kievlan, et al.,
Plaintiffs,

vs.

John Maier, et al.,
Defendants.

[Filed Aug. 21, 1975]

OPINION

This is an action brought by six senior citizens on behalf of themselves and as private attorneys general against Dahlberg Electronics, a manufacturer of hearing aid devices, and against local dispensers of those devices. The plaintiffs' claims for damages against the dispensers have been settled. By this motion for summary judgment, the Court is asked to determine the last remaining issue; namely, the legality of the manufacturer's advertisements of its hearing aids. The defense agrees that there are no contested issues of fact so that the remedy of summary judgment is proper.

The Law.

Plaintiffs' case is based on Health & Safety Code § 26463(m) which provides as follows:

> "It is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

. . . (m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness.

Also relevant are the following sections:

"§ 26464. An advertisement which is not unlawful under § 26460 [false advertising] is not unlawful under § 26463 if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices."

"§ 26465. Whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the conditions, disorders, or diseases named in § 26463, the department shall, by regulation, authorize the advertisement of any such drug or device as having a curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may consider necessary to the interests of public health."

"§ 26009. *Device.* "Device" means any instrument, apparatus, or contrivance, including any component, part, product, or by-product of a device, or accessory, which is used, or intended for use, for any of the following:

(a) In the diagnosis, cure, mitigation, treatment, or prevention of disease in man or any other animal.

(b) To affect the structure of any function of the body of man or any other animal."

The Advertisements.

Dahlberg Electronics advertises its hearing aids extensively in national publications. One ad in comic strip form is correctly described in plaintiff's brief as follows:

". . . it depicts the story of a mother who cannot understand the words at her daughter's graduation. Her doctor has told her she has mild nerve deafness, but he can not help her. She then reads a circular which implies that Dahlberg Hearing Aids can help mild nerve deafness. Visiting a Dahlberg dealer, her husband queries if anything can be done about her going deaf. The dealer tells her that 'medical experts generally agree that no effective cure has yet been found for this type of hearing loss.' She responds in despair, 'You mean it's hopeless?' Smiling, the dealer answers, 'It might have been different years ago, Mrs. Goodwin. But now, fortunately, modern science has created a tiny new electronic device made to help in most cases like yours . . .' The story then goes on to show how for the first time in years she can understand words clearly because of her Dahlberg Miracle Ear hearing aid. The reader is asked to send in a postcard which will tell her (or him) 'How I may be able to hear again more clearly in both ears without using hearing aids that have cords or tubes."

Other advertisements stress that Dahlberg's "Miracle Ear" hearing aid is designed for those who suffer from nerve impairment or mild nerve deafness and that the device will allow the wearer to hear more clearly.

The advertising campaign has been effective. Between January 1, 1972 and February 14, 1973, 11,903 postcard responses were received by Dahlberg from California residents who were then referred to local Dahlberg dealers.

Plaintiffs' Contention.

Plaintiffs' position can be stated in the form of a syllogism:

1. The statute prohibits the advertising of a device represented to have any effect on disorders of the ear including hearing loss.

2. Defendant's advertising claims effectiveness to compensate for hearing loss in cases of nerve impairment or nerve deafness.

3. Therefore, the statute prohibits advertising such as defendant's.

Defendant's Contention.

It is the defendant's basic position that § 26463 prohibits only the claim that the product or device has therapeutic or curative effect as distinguished from the assertion of a claim that the device merely compensates for the disorder or condition the way a prosthesis does for loss of a limb. This argument is drawn primarily from § 26465 which provides that if the Department of Health determines a type of self-medication to be medically safe for any of the conditions listed in § 26463, it may authorize the advertisement of the drug or device "as having a curative or therapeutic effect . . ."

The defendant's contention is not persuasive.

One. The language of § 26463 is sweeping; it prohibits the advertising of a device represented to have *any* effect. The use of the word "any" in a statute negatives the suggestion that the law was to be given a restrictive interpretation. *Emmolo v. So. Pacific,* 91 C.A.2d 87 (1949); *In Re Wymans Estate,* 208 C.A.2d 489 (1962).

Two. Granting that § 26463 and § 26465 have to be construed together, defendant is not aided. The words "curative" and "therapeutic" are used in the disjunctive in § 26465. Each has its distinctive meaning; therapy is obviously a far broader and more generic concept than cure. Products or devices which compensate for a loss accomplish a therapeutic purpose, as that term is ordinarily understood. A thyroid pill compensates for thyroid

deficiency; taking such medication does not cure such disorder but it has the therapeutic effect of permitting a person suffering from that condition to lead a normal life. The same can be said of insulin, crutches, prostheses and hearing aids.

Three. That § 26463 should be given a broad construction is also apparent from the legislative policy underlying the Pure Drugs Act. Basically the purpose of that legislation was to (1) encourage the general public to seek professional care for the conditions listed; and (2) prevent the commercial exploitation of the general public by the advertising of drugs or devices which may be useful but whose efficacy in particular cases cannot be determined by laymen. § 26464, § 26465; *People v. Ryan,* 101 C.A.2d 927, 931 to 932 (1951). Those policy considerations clearly apply to hearing aids, devices which help some persons suffering from impaired hearing and do not help others. As people with hearing defects desperately want help, they are especially suggestible. Finally, the devices are expensive; and they are needed primarily by the elderly, a class traditionally the objects of legislative solicitude and entitled to it.

Attorney's Fees.

Plaintiffs seek attorney's fees because they brought this action as private attorneys general; they claim that their efforts culminated in a decision yielding substantial benefits to a broad class of citizens. The doctrine authorizing the award of attorney's fees under those circumstances is entirely the creature of the federal courts, as the California Supreme Court has pointed out. *D'Amico v. Board of Medical Examiners,* 11 C.3d 1, 27 (1974). Now that the U. S. Supreme Court has overruled those decisions of the lower federal courts, the legal foundation for such an award has been removed. *Aleyska Pipe Line Serv. v. Wild-*

erness Soc., ... U.S. ....., 44 L.Ed.2d 141, 161, footnote 46 (1975).

An injunction will issue restraining defendant Dahlberg from making any performance claim in the advertising of its hearing aids. Nothing contained herein precludes defendant from advertising its places of business, that Dahlberg hearing aids are sold there, the prices of the instruments or any other information of that nature.

Dated: August 21, 1975.

HARRY F. BRAUER
Judge of the Superior Court

Exhibit C

Superior Court of the State of California
for the County of Santa Cruz

No. 51868

George Kievlan, Eris Gofinch, Charles Harrold, Mary Walker, Gladys Faustine, Minnie Carp, individually, and on behalf of the general public,
Plaintiffs,
vs.
John Maier, L. A. Stacey, Professional Hearing Aid Center, an individual Proprietorship; Dahlberg Electronics, a Corporation; Detection Science, a Corporation; and Doe 1 through Doe 20,
Defendants.

[Filed Mar. 22, 1976]

JUDGMENT

The above-entitled cause came on pursuant to Plaintiffs' Motion for Summary Judgment on August 13, 1975, in Department III of the above-entitled Court, the Honorable Harry F. Brauer, Judge presiding. Plaintiffs appeared by James Rumble, Diane Greenberg and Richard Pearl, their attorneys, and Defendants Dahlberg Electronics, Inc. and Detection Sciences, Inc., appeared by their attorneys, Thomas F. Nelson and Fred Hollander.

Said cause having been heard, documentary evidence presented by both plaintiffs and defendants having been received and admitted without objection, the Court having rendered its decision in favor of plaintiffs and against

defendants, as reflected in its opinion of August 21, 1975, the Court having caused to be made and filed its written Findings of Fact and Conclusions of Law.

It Is Ordered, Adjudged And Decreed that Plaintiffs George Kievlan, Eris Gofinch, Charles Harrold, Mary Walker, and Gladys Faustine have judgment against Defendants Dahlberg Electronics, Inc. and Detection Sciences, Inc. and that Defendants be and they hereby are permanently enjoined and restrained from advertising their hearing aids in California by representing that said hearing aids have any effect on diseases or disorders of the ear, or auditory apparatus, including hearing loss and deafness.

Dated: March 17, 1976

HARRY F. BRAUER
Judge of the Superior Court

Judgment entered on March 22, 1976, in Judgment Book, Vol. 148, page 320.

RICHARD C. NEAL
Clerk

By: JOAQUINA AZEVEDO
Deputy

Approved as to Form:

By: /s/ THOMAS F. NELSON
Attorney for Defendants

Exhibit D

In the Court of Appeal
State of California

First Appellate District

Division Four

No. 40017

George Kievlan, et al.,
Plaintiffs, Respondents and Appellants,
vs.
Dahlberg Electronics, Inc., et al.,
Defendants, Appellants and Respondents.

BY THE COURT:

The petition for a rehearing filed in the above entitled cause is hereby denied.

Dated: April 14, 1978

Caldecott, P.J.

Exhibit E

Order Due
June 19, 1978

In the Supreme Court
of the State of California
In Bank

Kievlan et al
Plaintiffs and Appellants

v.

Dahlberg Electronics et al
Defendants and Appellants

Bird, C.J., did not participate.

[Filed Jun 15, 1978]

ORDER DENYING HEARING
After Judgment by the Court of Appeal
1st District, Division 4, Civil No. 40017

Defendant's petition for hearing DENIED.

Manuel, J., is of the opinion that the petition should be granted.

TOBRINER
Acting Chief Justice

Exhibit F

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In the Court of Appeal
State of California

First Appellate District

Division Four

1 Civil No. 40, 017

George Kievlan, et al.,
Appellees,

vs.

Dahlberg Electronics, Inc., et al.,
Appellants.

[Filed Sep. 1, 1978]

NOTICE OF APPEAL TO THE SUPREME COURT
OF THE UNITED STATES

To the Clerk of the Above Entitled Court:

Notice Is Hereby Given that Dahlberg Electronics, Inc. and Detection Sciences, Inc., the appellants above-named, hereby appeal from the final Judgment of the Court of

Appeal of the State of California, affirming the Judgment of the Superior Court of the State of California, entered in this action on March 21, 1978, and which became final on June 15, 1978.

This appeal is taken pursuant to 28 U.S.C. § 1257(2).

Dated: August 31, 1978.

Stanley Walsh
David P. Dawson
Michael P. Carbone
Jordan, Walsh, Lawrence, Dawson & Carbone

By /s/ MICHAEL P. CARBONE
Attorneys for Appellants

(Proof of Service omitted)